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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,181	10/06/2005	Richard Walmsley	30276/04004	6821

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EXAMINER	
HUNTER, RONALD A	

ART UNIT	PAPER NUMBER
4185	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,181	WALMSLEY, RICHARD	
	Examiner	Art Unit	
	RONALD HUNTER	4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to application no. 10/519181filed on 09/12/2008.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 2, 5, & 8** are rejected under 35 U.S.C. 102(b) as being anticipated by **Van de Bergh (US Patent 5,068,515 A)**.

Regarding claim 1, Van de Bergh et al. invention discloses an apparatus for homogenizing the non-homogeneous light distribution of a laser beam (5) for the sharp-edged irradiation of an area, having a laser beam source, focusing optics (4) for focusing the laser beam, *(column 4, lines 46-49)*; an apparatus wherein the microscope has means for coarse adjustment and fine adjustment, *(column 5, lines 12-14)*.

Regarding claim 2, Van de Bergh et al. invention discloses an apparatus wherein the microscope has means for coarse adjustment and fine adjustment, *(column 5, lines 12-14)*.

Regarding claim 5, Van de Bergh et al. invention discloses an apparatus for homogenizing the non-homogeneous light distribution of a laser beam for the sharp-

edged irradiation of an area, having a laser beam source, focusing optics for focusing the laser beam, (where in (7) is the area to be treated) *(column 4, lines 46-49)*.

Regarding claim 8, Van de Bergh et al. invention discloses an apparatus for use in photodynamic therapy (photochemotherapy) *(Abstract, lines 3-5)*.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Van de Bergh (US Patent 5,068,515 A)** in view of **Segal (US Patent 6033431 A)**.

Regarding claim 3, Van de Bergh et al. fail to teach said apparent source size of said laser beam being greater than that required as a minimum condition for classification of said device as a Class I Laser.

However, Segal teaches in accordance with the foregoing specification of the laser diode, the laser light energy is generated at a fundamental wavelength of 1064 nm at an output power level from about 100-800 mw. In other implementations the laser light wavelength may be as high as about 2500 nm and power of up to 1000 mw *(column 7, lines 33-38)*.

6. It would be obvious to one of ordinary skill in the art to modify the teachings of Van de Bergh et al. with laser light energy generated at fundamental wavelength of 1064 nm at an output power level from about 100-800 mw of Segal.

Doing so would fulfill conditions necessary for efficiently using the device to test effected areas.

7. **Claims 4, 8, & 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van de Bergh (US Patent 5,068,515 A)** in view of **Levy (US 6100290 A)**.

Regarding claim 4, Van de Bergh et al. fail to teach a device wherein said laser generating means includes a laser emitting diode.

However, Levy teaches animals given transdermal irradiation using a box containing narrow spectrum light emitting diodes (690 nm±10 nm) for 20 min (15 J/cm^2) *(column 17, lines 41-44)*.

8. It would be obvious to one of ordinary skill in the art to modify the teachings of Van de Bergh et al. with light emitting diodes of Levy.

Doing so would make production of device more cost effective and laser light emission more efficient.

Regarding claim 9, Van de Bergh et al. fail to teach a device wherein said medical diagnostic or therapeutic process is the treatment of lymphedema.

However, Levy teaches animals given transdermal irradiation *(column 17, lines 41-42)*.

9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention Van de Bergh et al. for treatment fo

lymphedema as implied by Levy, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovery basis of its suitability for the intended use as a matter of obvious design choice.

Doing so would make the device more marketable and suitable for specific therapeutic purposes.

10. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Van de Bergh (US Patent 5,068,515 A)** in view of **Narciso (US Patent 5231684 A)**.

Regarding claim 6, Van de Bergh et al. fail to teach a device wherein said optical homogenizer includes a microlens array.

However Narciso et al. teach microlens attached to the treatment end of the optical fiber to distribute light from the fiber into a desired pattern or intensity distribution (*column 1, lines 15-17)*.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the teachings of Van de Bergh et al. with the microlens attached to the treatment end of the optical fiber to distribute light from the fiber into a desired pattern or intensity distribution of Narciso et al.

Doing so would make production of device more cost effective and laser light emission more efficient.

12. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Van de Bergh (US Patent 5,068,515 A)** in view of **Physical Optics Corporation** (http://statusreports.atp.nist.gov/reports/93-01-0205PDF.pdf).

Regarding claim 7, Van de Bergh et al. fails to teach a device wherein said optical homogenizer includes a holographic diffuser.

However Physical Optics Corporation, teaches holographic diffusers also can "homogenize" light beams, which can be descried as restructuring light beams into a uniformly diffused beam without internal structure or "hot spots," regardless of the source *(pg. 2, par 1, lines 5-9)*.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the teachings of Van de Bergh et al. with holographic diffusers that also can "homogenize" light beams, which can be descried as restructuring light beams into a uniformly diffused beam without internal structure or "hot spots," regardless of the source of Physical Optics Corporation.

Doing so would make production of device more cost effective and laser light emission more efficient.

14. **Claims 10 & 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van de Bergh (US Patent 5,068,515 A)** in view of **Wynne (US 6165170 A)**.

Regarding claim 10, Van de Bergh et al. fail to teach a positioning said device at a predetermined distance and orientation from a surface according to a requirement of said medical purpose.

However, Wynne et al. teach a positioning system in means for positioning a laser and camera during a surgical procedure *(view Fig. 5)*.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the teachings of Van de Bergh et al. with the positioning system of Wynne et al.

Doing so would increase mobility, precision and therapeutic potential of device.

Regarding claim 11, Van de Bergh et al fail to teach a positioning means including a frame, said frame adjustably attached to said device and when in use for medical diagnostic or therapeutic purpose providing an abutment surface relative to said treatment area.

However, Wynne et al. teach thus, it is desirable to develop a registration, well known in the art, between the area for treatment on the patient and the coordinate frame of the robot (see e.g., Computer Surgery, pp. 75-97) *(column 11, lines 3-6)*.

16. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the teachings of Van de Bergh et al. with the positioning system of Wynne et al.

Doing so would increase mobility, precision and therapeutic potential of device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention: **Case (US 4547037 A),**

Cecchetti et al. (US 5509917A), Fujimoto et al. (US 5982524 A), Koop (WO 9518984 A1), and Golub et al. (SU1561062 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUNTER whose telephone number is (571)270-7133. The examiner can normally be reached on Monday - Friday, 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUNTER/
Examiner, Art Unit 4185
/Terrell L Mckinnon/
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